disagree with this however applicants very much do disagree with the examiners' incorrect application of §102 to urge that claim 12 is anticipated.

The anticipation rejection in item 2 of the Action is incorrect as a matter of law. A patent claim is anticipated when the claimed invention was patented or described in a printed publication in the United States or a foreign country more than one year prior to the date of the application in the United States from which the patent issued. 35 USC §102(b). "For a prior art reference to anticipate in terms of 35 USC §102, every element of the claimed invention must be *identically* shown in a single reference." *Diversitech Corp. v Century Steps, Inc.*, 850 F.2d 675, 677 (Fed. Cir. 1988) (emphasis added.)

An anticipation rejection is only proper when the "claimed subject matter is identically disclosed or described in 'the prior art,' without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *In re Arkley*, 172 USPQ 524, 526 (CCPA 1972); *see also Akzo N.V. v. International Trade Commission,* 1 USPQ 2d 1241, 1246 (Fed. Cir. 1986); *Ex parte Lee,* 31 USPQ 2d 1105, 1108 (BPAI 1993). Every element of the challenged claim must be disclosed within this single reference. *PPG Industries Inc. v. Guardian Industries Corp.,* 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). Absence from the reference of any claimed element negates anticipation *Kloster Speedsteel AB v. Crucible Inc.* 23 USPQ 160 (Fed. Cir. 1986).

The examiner has picked and chosen for portions of Floyd to create with hindsight the arguments that claim 12 is not novel.

The rejection is factually flawed as well – every element of claim 12 is not identically disclosed in Floyd. Attention is directed to the term "solid pharmaceutical dosage form" in claim 12. Although Floyd does describe on column 1, line 41 an oral tablet formulation nowhere in the specification is the stability of the tablet ever tested for the compound 3-`amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one. Floyd's specification makes it clear in column 2, lines 28 to 34 that it is the injectable formulation (which is not a solid dosage form) which has been hampered by the instability of lamotrigine in aqueous media and that lamotrigine is hydrolytically decomposed to the 3-amino compound. The testing carried out in the specification in column 6, lines 10 to 18 which is reported in table 2 is carried out on the lyophilized formulation. This formulation although solid, is not a pharmaceutical dosage form.

One can't administer the lyophilized formulation directly to a patient without reconstitution into the i.v formulation.

The examiner "picking, choosing, and combining various disclosures not directly related to each other" as in *Arkley* has erred in finding claim 12 lacks novelty. The piecing together of portions of the specification which are clearly not designed to be read together does not anticipate the present invention.

In item 4 of the Official Action claim 15 is rejected as being unpatentable over Floyd together with a secondary reference while in item 5 of the Official Action all claims are rejected on the basis of four documents. Both of these rejections are unsound and should be withdrawn.

As explained in the above remarks addressing Floyd applied as an anticipation, claims 14 and 15 are also limited to solid pharmaceutical dosage forms. As Floyd fails to suggest to the person skilled in the art that lamotrigine in solid pharmaceutical dosage forms could degrade to the 3-amino compound then the teaching of Papadoyanis that standard solutions of a completely different compound could be used are not relevant to the determination of nonobviousness.

Dreassi discussed the testing of lamotrigine in human plasma -- again a situation very different to a solid pharmaceutical dosage form.

Qualia discusses the compound chlorothalidone and DeAngelis discusses the compound cinromide, both very different drugs to lamotrigine so neither reference can add anything to the disclosure of Floyd, because Floyd does not suggest that lamotrigine may degrade to compound A in solid pharmaceutical dosage forms. Qualia and DeAngelis can in no way add to this teaching. The present claims are inventive thereover.

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration, entry of this response and allowance are solicited.

Respectfully submitted,

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